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THE ASSESSMENT OF DIABETIC POLYNEUROPATHY IN DAILY CLINICAL PRACTICE: REPRODUCIBILITY AND VALIDITY OF SEMMES WEINSTEIN MONOFILAMENTS EXAMINATION AND CLINICAL NEUROLOGICAL EXAMINATION

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Polyneuropathy is present in over 80% of both type 1 and 2 diabetic patients with foot lesions.⁶ A reduction in the incidence of foot ulcerations can be achieved if polyneuropathy is identified at an early stage.^{1,5,17}

For the detection of diabetic polyneuropathy in daily clinical practice a simple, sensitive, and inexpensive screening method is required. Previous studies have indicated that both the Semmes Weinstein monofilaments examination (SWME) and the clinical neurological examination (CNE) can possibly be useful for diagnosing diabetic polyneuropathy in daily clinical practice and, moreover, may even help in identifying patients at risk for amputations.^{4,11,14,16}

The aim of the present study was to assess the reproducibility of both the SWME and the CNE in

type 1 and type 2 diabetic patients. Moreover, the sensitivity and specificity of both modes of examination were quantified, using vibration perception thresholds (VPT) as “gold standard.”

MATERIALS AND METHODS

Subjects. Sixty-eight diabetic patients participated in the study, 36 males and 32 females, with a mean age of 51.6 years (range 20–71) and a mean diabetes duration of 17.6 years (range 1–50). The neuropathy status at the time of recruitment of the patients was unknown. Individuals with polyneuropathy due to other causes were excluded from the study. The participants were asked to visit the research ward on two separate days with an interval of 2–4 weeks. Both the SWME and the CNE were performed by two different observers on one of the days, and repeated by one of these two observers on the other day. At the first visit, VPT was assessed by a third independent observer. On both occasions the observers were blinded to the results of the tests carried out by the other observers. Approval was granted by the ethical committee of the Free University Hospital.

SWME. During the SWME, the monofilaments were applied on both feet at three different sites (first toe, medial surface, and base of the third metatarsal bone). Three sizes of monofilaments were used for this study; 4.17 (1 g force), 5.07 (10 g force),

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and 6.10 (75 g force).^{10,11} The SWME threshold was defined as the total number of times the application of the monofilaments was not felt, and could vary between 0 and 18.

CNE. The CNE was quantified on the basis of a previously developed scoring system, which has been described in an earlier report.¹⁶ The CNE involves clinical testing of (1) sensory modalities (pinprick, light touch, vibration, and position sense) of the feet; (2) anatomic level below which light touch sensation is impaired; (3) muscle strength of the feet; and (4) ankle reflexes. The total score of the CNE could vary between 0 and 37.

VPT. The VPT of the foot was assessed with a Vibrometer (Somedic, Stockholm, Type 4). Details of this examination, and age-related reference values, have been described previously.^{8,13} Values \geq mean of age-related reference values + 2 standard deviations (SD) were considered to indicate the presence of polyneuropathy.

Statistical Analysis. The mean value and standard deviation of all measurements were calculated for the tests compared. The within-subject standard deviation (within-subject SD), the coefficient of variation (ratio of within-subject SD and mean of measurements), and the Pearson correlation coefficient with corresponding 95% confidence intervals (95% CI) were computed as measures of reproducibility.²

For selecting the best diagnostic cutoff point on the scale of measurement, the receiver operating characteristics (ROC) curve method was used.^{3,15} Sensitivity and specificity figures were compared by

calculating the area under the curves (AUC) and the significance of the difference between these areas.⁹

The Pearson correlation coefficient (95% CI) was used to measure the degree of association between the results of the SWME and the CNE.

RESULTS

Reproducibility. The SWME and the CNE were assessed in 64 patients on two separate occasions. The measures of reproducibility of the SWME and the CNE assessments are presented in Table 1.

ROC Curves, Sensitivity, and Specificity. For calculating sensitivity and specificity figures, the VPT was used as "gold standard." The best diagnostic cutoff point, at which maximum sensitivity and reasonable specificity figures were achieved, was >0 for the SWME and >4 for the CNE. When both examinations were performed by the same observer, the AUC \pm standard error (SE) of the CNE (0.86 ± 0.05) was significantly larger than that of the SWME (0.77 ± 0.06) ($P = 0.01$).

Using the best cutoff point, sensitivity figures of the SWME were 87.5% and 95.8%, respectively, and specificity figures were 61.4% and 45.5%, respectively, for the two different observers. Sensitivity figures of the CNE were 91.3% and 82.6%, respectively, and specificity figures were 63.4% and 60.9%, respectively.

Association between Measurements. Correlations between the SWME and the CNE were strong, and highly significant (correlation coefficients ranging from 0.69 to 0.83).

Table 1. Test-retest reproducibility of Semmes Weinstein monofilaments examination and clinical neurological examination assessments of diabetic polyneuropathy.

	Pooled data [mean (SD)]	Measures of reproducibility		
		Within-subject SD	Coefficient of variation	Correlation coefficient (95% CI)
SWME (\log_{10})				
Intraobserver	0.39 (0.35)	0.16	0.41	0.80
Test-retest*				(0.69–0.87)
Interobserver	0.40 (0.37)	0.18	0.45	0.77
Test-retest†				(0.65–0.85)
CNE				
Intraobserver	7.15 (6.29)	2.93	0.41	0.79
Test-retest*				(0.68–0.87)
Interobserver	7.15 (5.96)	2.76	0.39	0.79
Test-retest†				(0.68–0.87)

SWME, Semmes Weinstein monofilaments examination; CNE, clinical neurological examination. Outcomes of SWME: \log_{10} -transformed (range from 0 to 1.3).

*One observer on two separate days.

†Two observers on the same day.

DISCUSSION

In this study the reproducibility of both the SWME and the CNE was assessed, because these modes of examination are currently used for the detection of diabetic polyneuropathy in daily clinical practice. We calculated the within-subject SD, because it quantifies the scatter of the measured values around the mean of the subjects. Because the within-subject SD does not permit a comparison of methods with different scales of measurement, we also computed the coefficient of variation and, in addition, the test-retest correlation coefficients.

The results show that both modes of examination are sufficiently reproducible for the assessment of diabetic polyneuropathy in daily clinical practice. This finding is in accordance with the small number of reproducibility studies that have been reported previously.^{7,10,12} To our knowledge, no other data on the reproducibility of the SWME in diabetic patients are available.

By calculating the AUC, the ROC method allows comparison between competitive methods of examination.⁹ In the present study, the AUC of the CNE was significantly larger than the AUC of the SWME, indicating a greater discriminating ability of the CNE in comparison with the SWME.

Our results also show that the outcomes of the SWME and the CNE are strongly correlated, which indicates construct validity of both methods of examination.

In conclusion, the results of the present study show that the SWME and the CNE are both sufficiently reproducible and, in addition, reasonably sensitive and specific for diagnosing diabetic polyneuropathy in daily clinical practice.

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